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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,404	05/15/2002	Masamichi Okada	Q68135	2114

7590 03/26/2003
Sughrue Mion
2100 Pennsylvania Avenue NW
Washington, DC 20037-3213

EXAMINER

JIANG, SHAOJIA A

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 03/26/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/031,404

Applicant(s)

OKADA ET AL.

Examiner

Shaojia A. Jiang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 December 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-4 and 6-11 is/are pending in the application.
- 4a) Of the above claim(s) 7-11 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 2-4 and 6 is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 2-4 and 6-11 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10-11.
- 4) ☒ Interview Summary (PTO-413) Paper No(s) 12.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

This Office Action is a response to Applicant's amendment and response filed on December 30, 2002 in Paper No. 10 wherein claims 2-4 and 6 have been amended and claims 1 and 5 are cancelled, and claims 7-11 are newly submitted. Currently, claims 2-4, 6, and 7-11 are pending in this application.

Applicant's declaration of Masamichi Okada, Ph.D. (inventor) submitted December 30, 2002 in Paper No. 9 under 37 CFR 1.132, is acknowledged.

The following is a new rejection necessitated by June 17, 2002 in Paper No. 8, wherein all original claims are cancelled and the limitations in the new claims have been changed.

It is noted that the newly claims 7-11 are drawn to a method for the treatment herein that is independent and distinct from the invention originally claimed, which is entirely directed to a pharmaceutical composition herein.

Since applicant has received an action on the merits for the originally presented invention, according to MPEP § 819, the general policy of the Office is not to permit the applicant to shift to claiming another invention.

It is noted that the newly claims 7-11 are drawn to a method for the treatment herein comprising any compound having mG1uR1 antagonistic activity that is independent and distinct from the invention originally claimed, which is solely directed to a pharmaceutical composition comprising a specified compound herein in the pending claims 2-4, and 6.

It is also noted that the scope of composition employed in the newly submitted method is much broader than the claimed composition in the pending claims 2-4, and 6. Therefore, the pharmaceutical composition employed in the method is not the same composition in the pending claims 2-4, and 6.

The following is new Restriction Requirement necessitated by Applicant's amendment filed December 30, 2002 in Paper No. 10.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 2-4, and 6 drawn to a pharmaceutical composition comprising administering a specified compound herein, classified in class 514, subclass 397 and 438 for example.
- II. Claims 7-11 drawn a method of the treatment for improving neuropathic pain comprising a compound having mG1uR1 antagonistic activity, classified in class 514, subclass 1+.

In the instant case, the original invention (claims 1-6) is drawn to a composition comprising a specified compound herein, whereas the invention of newly submitted claims 7-11 is drawn to a method of the treatment for improving neuropathic pain. The original invention and the newly claimed invention are separate and distinct, related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be

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practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, for example, morphine -- which is materially different from the product as claimed, may be used in a method for the treatment of neuropathic pain in a mammal.

Thus, the original invention and the newly claimed invention are seen to be separate and distinct inventions. Note that a reference to the composition herein would not necessarily be a reference to the method of treatment herein under 35 USC 103. The composition and method herein have separate consideration as to patentability.

Therefore, claims 7-11 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. See the interview summary in Paper No. 12.

A complete reply to the Office Action must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Applicant's amendment rewriting the objected claim 6 which is directed to employing a particular novel compound in the claimed composition herein, in independent form including all of the limitations of the base claim and any intervening claims, as indicated in the previous Office Action; and canceling claims 1 and 5, and amending claims 2-4 to be dependent from claim 6, filed December 30, 2002 in Paper No. 10, have been considered and are sufficient to remove the rejections under 35 U.S.C. 112, first and second paragraph, and all prior art rejections under 35 U.S.C. 102(b) and under 35 U.S.C. 103(a) of record in the previous Office Action July 30, 2002. The pending claims 2-4, and 6 are seen to be allowable since the claimed

composition herein employing the specified compound in claim 6 is not seen to be taught or fairly suggested by the prior art.

Applicant's amendment necessitated the new restriction presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (703) 305-1008. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

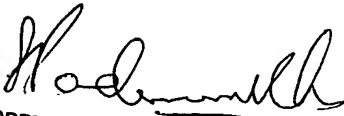
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.

S. Anna Jiang, Ph.D.
Patent Examiner, AU 1617
March 12, 2003


SREENI PADMANABHAN
PRIMARY EXAMINER 5/23/03